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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,523	04/17/2001	Yong-Qian Wu	23754X	5679
29728	7590	05/11/2004	EXAMINER	
GUILFORD PHARMACEUTICALS C/O FOLEY & LARDNER 3000 K STREET, NW WASHINGTON, DC 20007-5143			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/835,523

Applicant(s)

WU ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,11-40 and 49-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-10, and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's election with traverse of group I in the response of 12-17-03 is acknowledged. The traverse is on the ground that there is no burden of searching based on the evidence and explanation given. The traversal is not found persuasive for the following reasons:

- There are four different formulae. Each formula differs from each other by the groups attached to the ring nitrogen.
- Each formula has a core ring that varies from 5-member to 6-member to 7-member. Thus, for each formula, at least three different searches (one for each ring size) are needed. Therefore, for four formulae, at least twelve different searches are needed.
- Furthermore, the inventions of groups 5, 10, 15, and 20 require the additional search for the neurotrophic factor.
- Additionally, restrictions are discretionary, and there is no per se rule to prevent restriction in an office action after the first office action.

Because these inventions are distinct for the reasons given above and the search required for Group 1 is not required for Groups 2-20, restriction for examination purposes as indicated is proper. The restriction is made FINAL.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 3, 7-10, and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claim 3 lacks antecedent basis because it recites species that do not belong to the genus of formula I in claim 1. They are species of substituted *pyrazolidinecarboxylate* or *perhydropyridazinecarboxyalte*, in which the ring N is substituted with  $-C(=O)-O-$ , and not  $-C(=O)-C(=O)-R_2$  as presented in formula (I) of claim 1.
- b. Claim 7 recites the term “*affecting*”. The metes and bounds of said term cannot be determined because it is not clear if “*affecting*” means ‘increasing’ or ‘decreasing’ or ‘normanlizing’ a neuronal activity. This ambiguity renders claim 7 indefinite.
- c. Claims 8-10 are rejected as being dependent on claim 7.
- d. Claim 48 is rejected because it is not what formulation is intended (powder? tablet? syrup? Or suspension?). Also, it is not clear what proportions are needed.

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-4, 7-10, and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,417,189 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

a. The compounds of claim 2 in US'189 read on the subgenus of formula I of the instant claims 1, 4, and 7 when it has the following substituents:

- i.  $n$  equals 2 (i.e., the core ring is a 6-membered ring of *perhydropyridazine*);
- ii.  $X$  is O;
- iii.  $R_1$  is  $-\text{COR}_3$ ;  $R_3$  is a substituted alkyl group;
- iv.  $R_2$  is an alkyl group;

b. Note, the first two compounds, and the last compounds of claim 2 in US'189 are also recited in the instant claim 3.

c. The formula I of US'189 differs from the instant formula I by not reciting a 5-membered ring (i.e.,  $n = 1$ , or *pyrazolidine*), and a 7-membered ring (i.e.,  $n = 2$ , or *1,2-diazepane*).

d. However, with regard to compounds of 6-membered ring (i.e., *perhydropyridazine*), it would have been obvious to one skilled in the art because the disclosed species fall within the subgenus of the instant formula I.

4. For the analysis set forth above, the pharmaceutical composition claim 3 in US'189 renders obvious the instant pharmaceutical composition claim 4 when n equals 2. Likewise, the method claims 4-7 render obvious the instant method claims 7-10. Although claim 7 recites "*affecting*", it would have been obvious to one skilled in the art that "*affecting*" would result in "*treating*". Since the instant pharmaceutical composition claim 4 is obvious, claim 48 (drawn to a method of making a pharmaceutical composition) is also obvious.

### ***Claim Objections***

5. Claims 1 and 4 are objected to because of the following informalities: Punctuation is required between the alternative hetero and carbocyclic rings. Appropriate correction is required.

6. Claim 2 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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In the instant case, the intended use of "*non-immunosuppressive*" in claim 2 does not result in a tangible structural difference between the product of the independent claim (i.e., claim 1), and the product of the dependent claim (i.e., claim 2). In the absence of such a structural difference, claim 2 is considered as a substantial duplicate of claim 1. The recitation of "*non-immunosuppressive*" is, therefore, not afforded critical weight, and fails to further limit the product claim 2.

***Non-elected claims***

7. Claims 5, 6, 11-40, and 49-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected with traverse, there being no allowable generic or linking claim. Applicant is suggested to cancel non-elected subject matter (i.e., all the ring structures represented by R<sub>1</sub>), and the non-elected claims 5, 6, 11-40, and 49-51.

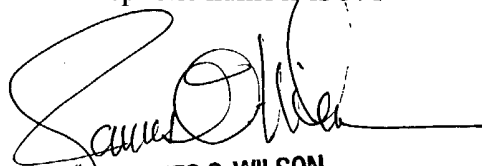
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (~10 am ~ 6:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



T. Truong  
April 26, 2004



JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600